DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 25 2003

Mr. Gregory Gonot
Deputy Attorney General
State of California
Department of Justice
1300 I Street
Sacramento, California 95814

Re: Opinion No. 03-601

Dear Mr. Gonot:

I write in response to the letter of July 28, 2003, that your colleague, Rodney O. Lilyquist, sent the United States Food and Drug Administration (FDA) regarding the importation of prescription drugs from Canada into the State of California.

I. QUESTIONS PRESENTED

Mr. Lilyquist's letter asks nine separate questions about the potential liability associated with importing prescription drugs from Canada. All nine of the questions relate to one of three basic issues:

- Questions 1 – 6 query whether it is legal to purchase drugs from Canada and import them into the State of California.

- Questions 7 – 8 query whether the federal law in this area preempts the State of California (or a county or city within the state) from enacting a law that would legalize the importation of prescription drugs from Canada.

- Question 9 queries whether public pension funds such as CALPERS or CALSTRS can negotiate for Canadian prescription drug prices for their members.

II. SHORT ANSWER

FDA is very concerned about the safety risks associated with the importation of prescription drugs from foreign countries. In our experience, many drugs obtained from foreign sources that purport and appear to be the same as U.S.- approved prescription drugs have been of unknown quality. We cannot provide adequate assurance to the American public that the drug products delivered to consumers in the United States from foreign countries are the same products approved by FDA. For example, an American consumer recently ordered an FDA-approved anti-seizure medication called Neurontin from a website that purported to operate in

Canada and ship FDA-approved drugs from Canada into the United States. Nevertheless, the drug the consumer actually received had been manufactured in India, shipped from India, and was not approved by FDA for any use in the United States. In another instance, a website that purported to operate in Canada mailed insulin into the United States for use by an American with diabetes. Although the drug originally had been manufactured in the United States, it had not been appropriately refrigerated when shipped back into the country. The failure to refrigerate insulin promotes the degradation of the drug and renders it less effective. Unfortunately, however, the failure to refrigerate the product may not change its appearance, so American consumers may have no way of knowing their insulin has been mishandled abroad.

These safety concerns are reflected in the import provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), which strictly limit the types of drugs that may be imported into the United States. Congress enacted these provisions to create a relatively "closed" drug distribution system, which helps ensure that the domestic drug supply is safe and effective. Accordingly, if an entity or person within the State of California (including any state, county, or city program, any public pension, or any Indian Reservation) were to import prescription drugs into the State of California from Canada, it would violate FFDCA in virtually every instance. Furthermore, the drug importation scheme set forth by Congress preempts the State of California (and any city or county within the state) from passing conflicting legislation that would legalize the importation of certain drugs from Canada in contravention of the FFDCA.

III. ANALYSIS

1. Questions 1 – 6: The importation of prescription drugs from Canada

General Legal Framework

The starting point for our analysis is the legal framework applicable to imports of prescription drugs from Canada.[1]

First, virtually all drugs imported to the United States from Canada violate the FFDCA because they are unapproved (21 U.S.C. § 355), labeled incorrectly (21 U.S.C. §§ 352, 353), or dispensed without a valid prescription (21 U.S.C. § 353(b)(1)). Importing a drug into the United States that is unapproved and/or does not comply with the labeling requirements in the FFDCA is prohibited under 21 U.S.C. §§ 331(a), and/or (d).

FDA approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. 21 C.F.R. § 314.50. Generally, drugs sold outside of the United States are

[1] We will limit our discussion to drugs imported from Canada because your request is so limited. The legal analysis is the same for drugs imported from any foreign country.

not manufactured by a firm that has FDA approval for that drug. Moreover, even if the manufacturer has FDA approval for a drug, the version produced for foreign markets usually does not meet all of the requirements of the United States approval, and thus it is considered to be unapproved. 21 U.S.C. § 355. The version also may be misbranded because it may lack certain information that is required under 21 U.S.C. §§ 352 or 352(b)(2) but is not required in the foreign country, or it may be labeled in a language other than English (*see* 21 C.F.R. § 201.15(c)).

Second, with respect to "American goods returned," it is illegal for any person other than the original manufacturer of a drug to import into the United States a prescription drug that was originally manufactured in the United States and sent abroad (21 U.S.C. § 381(d)(1)). This is true even if the drug at issue were to comply in all other respects with the FFDCA. *Id.* Importing a drug into the United States in violation of section 381(d)(1) is prohibited under 21 U.S.C. § 331(t).

Thus, to ensure compliance with the FFDCA, any state or private entity that intends to import prescription drugs into the United States must ensure, among other things, that it only imports FDA-approved drugs that comply with the FDA approval in all respects, including manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. 21 C.F.R. § 314.50. The importer must also ensure that each drug meets all U.S. labeling requirements, and that such drugs are not imported in violation of the "American goods returned" language in 21 U.S.C. § 381(d)(1).

Practically speaking, it is extremely unlikely that any program in the state of California could ensure that all of the applicable legal requirements are met. Consequently, almost every time a city, county, or state program imported a drug from Canada, that program would violate the FFDCA. Moreover, individuals or programs that cause illegal shipments also violate the FFDCA. 21 U.S.C. § 331 ("The following acts and the causing thereof are hereby prohibited..."). Thus, neither the public nor private entities mentioned in Mr. Lilyquist's letter can avoid jurisdiction under the FFDCA by merely "facilitating" the sale of Canadian drugs to California citizens through a third-party internet service. [2]

With respect to questions 4 and 5 of Mr. Lilyquist's letter, please note that the preceding analysis applies also in the case of sovereign Indian nations located in the State of California. FDA considers Indian Reservations to be possessions of the United States within the meaning of 21 U.S.C. § 321(a)(2). Accordingly, FDA asserts complete jurisdiction over products within the purview of the FFDCA that are imported, purchased, or sold by an Indian reservation. *See FPC v. Tuscarora Indian Nation*, 362 U.S. 99, 116 (1960); *United States v.*

[2] The issue of whether persons may broker the sale of Canadian drugs through an internet operation is discussed more fully in Warning Letters that FDA sent to Rx Depot (March 21, 2003) and CanadianDiscountDrugs (June 30, 2003). A copy of those letters is enclosed and can also be obtained through FDA's website at www.fda.gov. They are particularly responsive to question number 6 in Mr. Lilyquist's letter, which queries whether an Indian nation may sell Canadian prescription drugs through a website to other residents of California.

Baker, 63 F.3d 1478, 1484 (9th Cir. 1995), *cert. denied*, 116 S. Ct. 824 (1996); *United States v. Funmaker*, 10 F.3d 1327, 1330 (7th Cir. 1993); *EEOC v. Fond du Lac Heavy Equipment and Construction Co.*, 986 F.2d 246, 248 (8th Cir. 1993).

With respect to question 6 of Mr. Lilyquist's letter, please note also that the preceding analysis applies to persons who import drugs into the United States on their person or on a bus. In those cases where the FFDCA prohibits the importation of a prescription drug, it makes no legal difference whether that drug has been imported through the mails, delivered by a private shipping company, or carried across the border on one's person. *See* 21 U.S.C. §§ 331 and 381.

FDA's Personal Importation Policy

There has been some recent confusion in the press about whether FDA's Personal Importation policy changes the law with respect to personal imports of pharmaceuticals. Recent advertisements in certain domestic newspapers and magazines have implied that Congress has made the personal importation of drugs a legal practice. Other advertisements and certain Internet sites have stated that personal importation of up to a 90-day supply of prescription medications is legal. Neither of these messages is true.

The Personal Importation policy is used to help guide the agency's enforcement discretion with respect to imports by individuals of drugs for their personal use. Under certain defined circumstances, as a matter of enforcement discretion, FDA allows consumers to import otherwise illegal drugs. Under this policy, FDA may permit individuals and their physicians to bring into the United States small quantities of drugs sold abroad for a patient's treatment of a serious condition for which effective treatment may not be available domestically. This approach has been applied to products that do not present an unreasonable risk and for which there is no known commercialization and promotion to persons residing in the U.S. A patient seeking to import such a product must also provide the name of the licensed physician in the U.S. responsible for his or her treatment with the unapproved drug product. *See* FDA Regulatory Procedures Manual, Chapter 9, Subchapter: Coverage of Personal Importation.

However, this policy is not intended to allow importation of foreign versions of drugs that are approved in the U.S., particularly when the foreign versions of such drugs are being "commercialized" to U.S. citizens. (Foreign versions are often what Canadian pharmacies offer to sell to U.S. consumers.) Moreover, the policy simply describes the agency's enforcement priorities; it does not change the law.

Potential Liability

There are many sources of civil and criminal liability for parties who violate the FFDCA. A court can enjoin violations of the FFDCA under 21 U.S.C. § 332. A person who violates the FFDCA can also be held criminally liable under 21 U.S.C. § 333. A violation of 21 U.S.C.

§§ 331(a), (d), or (t) may be prosecuted as a strict liability misdemeanor offense. *See United States v. Dotterweich*, 320 U.S. 277, 284 (1943); 21 U.S.C. § 333(a)(1). Any such violation that is committed with intent to defraud or mislead or after a prior conviction for violating the FFDCA may be prosecuted as a felony under 21 U.S.C. § 333(a)(2). Separately, it is also a felony to knowingly import a drug in violation of the "American goods returned" provision of 21 U.S.C. § 381(d)(1). *See* 21 U.S.C. § 333(b)(1)(A).

Those who can be found civilly and criminally liable include all who cause a prohibited act under the FFDCA. 21 U.S.C. § 331 ("The following acts and the causing thereof are hereby prohibited"). Those who aid and abet a criminal violation of the FFDCA, or conspire to violate the FFDCA, can also be found criminally liable under 18 U.S.C. §§ 2 and 371.

To date, FDA has focused its enforcement resources on those who commercialize the practice of importing drugs into the United States from abroad.[3] With respect to question 6 in Mr. Lilyquist's letter, please note that, as a matter of enforcement discretion, FDA generally has not seized drugs from those who have taken buses across the border and then brought foreign drugs back into United States for their own personal use. Instead, FDA has attempted to educate such citizens about the safety risks associated with consuming foreign drugs. Nevertheless, FDA retains the authority to bring an enforcement action in any case in which a provision of the FFDCA has been violated.

Please also note that, under current California law, state-sponsored importation of drugs from Canada for use in the state's Medi-Cal program may violate the statutory and regulatory requirements for this program. *See* West's Ann. Cal. Welf. & Inst. Code, § 14100, *et. seq*; Cal. Admin. Code tit. 22, § 50000, *et. seq*. For example, the importation of drugs from Canada may violate the Prudent Purchase of Drugs Program, 22 CCR § 51513.6, because the drug products are not "handled in accordance with the provisions of applicable federal and state law." In addition, we question whether the state would be potentially liable in tort if a California citizen were injured by a drug that the state purchased in violation of federal law. FDA has not researched and does not here advise you of any tort liability that may arise under state law, but we cite the issue as a possible concern.

2. Questions 7 and 8: Federal preemption

Federal preemption of state law is grounded in the Supremacy Clause of the United States Constitution. U.S. Const. art. VI, cl. 2. The Supremacy Cause states that: "This Constitution, and the Laws of the United States which shall be made in pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2.

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[3] *See, e.g.*, the Warning Letter that FDA sent to Rx Depot on March 21, 2003, the Warning Letter that FDA sent to CanadianDiscountDrugs on June 30, 2003, and the letter that FDA sent the Kullman Firm of New Orleans, Louisiana on February 12, 2003. A copy of the Kullman letter has also been enclosed for your review.

The Supreme Court has held:

> under the Supremacy Clause, the enforcement of a state regulation may be pre-empted by federal law in several circumstances; first, when Congress, in enacting a federal statute, has expressed a clear intent to pre-empt state law; second, when it is clear, despite the absence of explicit preemptive language, that Congress has intended, by legislating comprehensively, to occupy an entire field of regulation and has thereby left no room for the States to supplement federal law; and finally, when compliance with both state and federal law is impossible, or when state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

Capital Cities Cable, Inc. v. Crisp, 467 US 691, 698-99 (1984) (quotation marks and citations omitted); *see also English v. General Electric Co.*, 496 US 72, 78-79 (1990); *Association of Int'l Auto Mfrs., Inc. v. Abrams*, 84 F.3d 602, 607 (2nd Cir. 1996).

Courts have thus held that federal law preempts state law when, *inter alia*, Congress has intended to occupy a field of regulation comprehensively (termed "occupation of the field preemption") and when the federal law and the state law actually conflict (termed "implied conflict preemption"). *See English v. General Electric Co.*, 496 US at 78-79; *Choate v. Champion Home Builders Co.*, 222 F.3d 788, 792 (10th Cir. 2000).

Occupying the field

Congressional intent to occupy a field comprehensively can be shown any of three ways: 1) when, based on the pervasiveness of the federal regulation, it may be inferred that Congress "left no room for the States to supplement it"; 2) if the federal statute "touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject."; or 3) when the state regulation "may produce a result inconsistent with the objective of the federal statute." (emphasis added) *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 US 707, 713 (1985), *quoting Rice v. Santa Fe Elevator Corp.*, 331 US 218, 230 (1947).

In the instant matter, Congress set forth a comprehensive importation scheme in the FFDCA that strictly limits the types of prescription drugs that are allowed to be introduced into domestic commerce. For example, the "American goods returned" provision (21 U.S.C. § 381(d)(1)) was enacted in 1988 as part of the federal Prescription Drug Marketing Act. PL. 100-293 (April 22, 1988). In enacting the law, Congress cited the explicit goal of limiting the flow of drugs into the United States from abroad. In section 2 of the bill, Congress found, "[l]arge amounts of drugs are being reimported into the United States as American goods returned. These imports are a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping." *Id.* Clearly,

Congress enacted section 381(d)(1) and the other import provisions in the FFDCA with the goal of controlling the types of drugs that could be legally imported into the United States. The federal scheme is comprehensive in that it promulgates national standards that are to be applied equally to all ports of entry, regardless of the states in which they are situated. By definition, the scheme cannot allow the individual states to enact laws that erode the federal standards; otherwise, importers could simply circumvent the federal law by routing all their unapproved drugs into the state (or states) that allowed such imports. If the state of California were to enact a law that contravened the scheme, there is no question that the result would be inconsistent with the plain objectives of the FFDCA.

Implied conflict preemption

Implied conflict preemption can be shown in two ways: (1) where it is impossible to comply with both federal and state law; or (2) where the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. *See English v. General Electric Co.*, 496 US at 79.

In the instant matter, if the state were to enact import legislation that contravened the provisions of the FFDCA, those importing the drugs would find it impossible to comply with both the state and the federal law. Indeed, the drugs imported pursuant to the state law would still be illegal under federal law (*see* 21 U.S.C. §§ 331, 352, 353, 355, and 381), and those importing the drugs would be subject to civil or criminal liability in the federal courts (21 U.S.C. §§ 331, 332, and 333).

In addition, a state law authorizing the importation of certain drugs would frustrate the Congressional objectives enshrined in the import provisions of the FFDCA. As noted, Congress clarified the purpose behind 21 U.S.C. § 381(d)(1) when it passed the Prescription Drug Marketing Act. It concluded that American consumers are best protected by a "closed" drug system that strictly limits the types of products that may be imported into the United States. Any effort by the State of California to pass legislation conflicting with that scheme would stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress as expressed in the FFDCA.

3. Question 9: Public Pension Funds

As noted above, the import prohibitions in the FFDCA apply to both public and private entities. *See* 21 U.S.C. §§ 321(e) and 331. Thus, a public pension fund would be subject to the same liability as a private citizen for a violation of the import provisions of the FFDCA.

I. CONCLUSION

I hope that the preceding discussion is helpful to you. From a public health standpoint, FDA is very concerned about the kind of scenario described in your letter. In our experience, many

drugs obtained from foreign sources that purport and appear to be the same as FDA-approved prescription drugs have been of unknown quality. FDA approves a drug based on scientific data submitted by the drug sponsor to demonstrate that the drug is safe and effective. We cannot provide adequate assurance to the American public that the drug products delivered to consumers in the United States from foreign countries are the same products approved by FDA. Accordingly, the FFDCA strictly limits the types of prescription drugs that may be imported into the United States. Any state law that would legalize imports in contravention of the FFDCA would be preempted by federal law. Moreover, those importing drugs in violation of the FFDCA would be subject to liability under that statute, regardless of whether the importation was otherwise sanctioned by the state.

Nevertheless, we are aware that the high cost of some prescription drugs is a serious public health issue, and we have taken several steps in recent months to help reduce the cost of drugs in the United States without opening our borders to the potential dangers of foreign unapproved pharmaceuticals. These steps include new initiatives to accelerate approval of innovative medical procedures and drug therapies, changes to our regulations to reduce litigation that has been shown to delay unnecessarily access to more affordable generic drugs, and proposals to increase agency resources for the review and approval of generic drugs – products that are often far less expensive than brand name products and generally no more expensive in the United States than the generic drugs sold elsewhere in the industrialized world. The Administration is also working with the Congress on landmark legislation to provide a prescription drug benefit that will enable millions of America's seniors to receive coverage for their drugs in Medicare.

Thank you for your interest in this matter. If you need additional information, please feel free to contact me.

Sincerely,

William K. Hubbard
Associate Commissioner for Policy and Planning

Encl: FDA letter to the Kullman Firm (February 12, 2003)
FDA Warning Letter to Rx Depot (March 21, 2003)
FDA Warning Letter to CanadianDiscountDrugs (June 20, 2003)